GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4760
ANSWERED ON:09.05.2007
QUALITY OF INDIAN MEDICINES
Gaikwad Shri Eknath Mahadeo;Mane Smt. Nivedita

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Australia has expressed apprehensions on the quality of Indian medicines made out of herbs etc. as reported in the `Business Standard` dated April 1,2007;

(b) if so, the details of the facts reported therein;

(c) the reaction of the Government in this regard;and

(d) the steps taken by the Government to control the production of these medicines and safeguard their quality?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a)&(b): No formal communication has been received from Therapeutic Goods Administration of Australia regarding the alert issued by them as mentioned in the Business Standard report on 1st April, 2007. However, on the publication of a Research Article in the Journal of American Medical Association (JAMA) some time ago indicating presence of heavy metals above the permissible limits in some of the Ayurveda and Unani formulation collected by the Researchers from grocery stores from Boston area, some health alerts have been issued by some of the regulatory authorities regarding the presence of heavy metals above the permissible limit in some of the Ayurveda and Unani formulations.

(c)&(d): The Government have taken following steps:-
I. Government has introduced mandatory testing for heavy metals in all purely herbal Ayurveda, Siddha and Unani medicines to be exported with effect from 01.01.2006 onwards.This has been done to meet the regulatory requirements of importing countries.

II. State Drug Licensing Authorities have been directed to ensure full compliance by all ASU drug manufacturers of the provisions of Rule 161 (1) and (2) relating to displaying on the label of the container or in a leaflet to be inserted in the package of an ASU drug, the true list of all the ingredients used in the manufacture of the preparation together with the quantity of each of the ingredients incorporated therein.

III. Under Centrally Sponsored Scheme 2 9 State Drug Testing Laboratories have been strengthened and 2 6 Pvt. Drug Testing Laboratories and other NABL accredited laboratories have been approved for testing of ASU drugs in the country.

IV. A research project has been sanctioned to various laboratories of Council of Scientific and Industrial Research (CSIR) under the Golden Triangle Partnership Project to study the physiochemical characteristics of 8 most widely use Bhasmas and to carry out their toxicity studies.

V. Good Manufacturing Practices have been made mandatory for all Ayurveda, Siddha and Unani drug manufacturing units in the country.